



Press Release

Once-Weekly Exenatide LAR Clinical Study in Type 2 Diabetes Initiated

SAN DIEGO, CA, INDIANAPOLIS, IN and CAMBRIDGE, MA, March 24 /PRNewswire-FirstCall/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced that, following discussions with the U.S. Food and Drug Administration (FDA), a long-term comparator clinical study of a long-acting release (LAR) formulation of BYETTA(R) (exenatide) injection in patients with type 2 diabetes has been initiated. This study is designed to generate the type of safety and efficacy data that could form the basis of a New Drug Application (NDA).

The 30-week open-label, noninferiority study will assess whether once-weekly exenatide LAR is at least as effective in improving glucose control as twice-daily BYETTA. Approximately 300 subjects with type 2 diabetes who are not achieving adequate glucose control using diet and exercise with or without the use of oral antidiabetic agents will be randomized to one of two treatment groups. Subjects randomized to the exenatide LAR group will receive once-weekly subcutaneous injections of a single strength of exenatide LAR. Subjects randomized to the comparison group will receive twice-daily injections of 10 micrograms of BYETTA. Endpoints include change in hemoglobin A1C (a standard measure of glucose control), fasting blood glucose, body weight, and safety parameters. All participants who complete the randomized portion of the study will have the opportunity to continue in an extension study and receive once-weekly exenatide LAR.

In parallel with clinical activities, manufacturing process development and scale-up activities are underway. The material for this study is being manufactured at development scale, and the Companies are working to determine the overall manufacturing strategy. In December 2005, Amylin announced that it purchased a facility for the commercial production of exenatide LAR and expects to finalize the commercial manufacturing process for exenatide LAR by late 2008.

BYETTA was approved by the FDA in April 2005 for the treatment of type 2 diabetes as add-on therapy in patients who are not achieving acceptable blood sugar control despite using the commonly prescribed diabetes medications metformin, a sulfonylurea or a combination of both. Amylin, Lilly, and Alkermes are working together to develop a sustained release, subcutaneous injection of exenatide for the treatment of type 2 diabetes based on Alkermes' proprietary Medisorb(R) technology. Exenatide LAR has not been approved by the FDA for marketing in the United States.

About BYETTA

BYETTA is the first in a new class of drugs for the treatment of type 2 diabetes called incretin mimetics and exhibits many of the same effects as the human incretin hormone glucagon-like peptide-1 (GLP-1). GLP-1, secreted in response to food intake, has multiple effects on the intestine, liver, pancreas and brain that work in concert to improve blood sugar.(1)

About Incretin Mimetics

Incretin mimetics is a new class of therapeutic agents in the fight against diabetes. An incretin mimetic works to mimic the antidiabetic or glucose-lowering actions of naturally occurring human hormones called incretins. These actions include stimulating the body's ability to produce insulin in response to elevated levels of blood sugar, inhibiting the release of a hormone called glucagon following meals, slowing the rate at which nutrients are absorbed into the bloodstream and reducing food intake. BYETTA is the first FDA-approved agent of this new class of medications.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide(2) and more than 20 million in the United States.(3) Approximately 90-95 percent of those affected have type 2 diabetes, a condition where the body does not produce enough insulin and/or the cells in the body do not respond normally to insulin.(3) Diabetes is the sixth leading cause of death by disease in the United States(3) and costs approximately \$132 billion per year in direct and indirect medical expenses. Type 2 diabetes usually occurs in adults over the age of 40, but is increasingly common in younger people.(3)

According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of diabetes patients do not achieve target A1C levels (less than 7.0 percent according to American Diabetes Association guidelines(4)) with

their current treatment regimen.(5)

Important Safety Information for BYETTA(TM) (exenatide) injection

BYETTA(TM) (exenatide) injection improves blood sugar control in patients with type 2 diabetes who are taking metformin, a sulfonylurea, or both. BYETTA is not a substitute for insulin in patients whose diabetes requires insulin treatment. BYETTA is not recommended for use in patients with severe problems digesting food or those who have severe disease of the stomach or kidney. BYETTA has not been studied in children or pregnant women.

When BYETTA is used with a medicine that contains a sulfonylurea, low blood sugar (hypoglycemia) is a possible side effect. To reduce this possibility, the dose of sulfonylurea medicine may need to be reduced while using BYETTA. Other common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea is most common when first starting BYETTA, but decreases over time in most patients. BYETTA may reduce appetite, the amount of food eaten, and body weight. No changes in dose are needed for these side effects. These are not all the side effects with BYETTA. A health care provider should be consulted about any side effect that is bothersome or does not go away.

For complete safety profile and other important prescribing considerations, visit www.BYETTA.com.

About Amylin, Lilly, and Alkermes

Amylin Pharmaceuticals is a biopharmaceutical company committed to improving lives through the discovery, development and commercialization of innovative medicines. Amylin has developed and gained approval for two first-in-class medicines for diabetes, SYMLIN(R) (pramlintide acetate) injection and BYETTA(TM) (exenatide) injection. Amylin is located in San Diego, California with over 1200 employees nationwide. Further information on Amylin Pharmaceuticals and its pipeline in metabolism is available at www.amylin.com.

Through a long-standing commitment to diabetes care, Lilly provides patients with breakthrough treatments that enable them to live longer, healthier and fuller lives. Since 1923, Lilly has been the industry leader in pioneering therapies to help health care professionals improve the lives of people with diabetes, and research continues on innovative medicines to address the unmet needs of patients. For more information about Lilly's current diabetes products visit www.lillydiabetes.com.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

Alkermes, Inc. is a pharmaceutical company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. Alkermes' lead commercial product, RISPEDAL(R) CONSTA(R) [(risperidone) long-acting injection], is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and is marketed worldwide by Janssen-Cilag (Janssen), a wholly owned division of Johnson & Johnson. Alkermes' lead proprietary product candidate, VIVITROL(TM) (naltrexone for extended-release injectable suspension), is being developed as a once-monthly injection for the treatment of alcohol dependence. Alkermes has a pipeline of extended-release injectable products and pulmonary drug products based on its proprietary technology and expertise. Alkermes' product development strategy is twofold: Alkermes partners its proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies and it also develops novel, proprietary drug candidates for its own account. Alkermes' headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio.

This press release contains forward-looking statements, which involve risks and uncertainties within the meaning of the Private Securities Litigation Reform Act of 1995. There can be no assurance that actual results will not differ materially from the forward-looking statements discussed in this press release. These forward-looking statements include risks and uncertainties that current or future clinical trials will confirm previous results or that the trial discussed above will be completed when planned; risks and uncertainties that the results from the clinical trial discussed in this press release will meet primary endpoints or the clinical study will generate clinical data that could form the basis of an NDA submission; risks and uncertainties that Amylin will be able to complete manufacturing scale-up and construction and validation of its manufacturing facility on a timely basis, or at all; risks and uncertainties inherent in the collaboration with and dependence upon Lilly, Amylin and/or Alkermes; risks and uncertainties regarding the drug discovery and development process, including whether exenatide LAR will receive regulatory approvals, be commercialized or prove to be commercially successful. These and additional risks and uncertainties are described more fully in Amylin, Lilly and Alkermes' filings with the United States Securities and Exchange Commission, including Amylin's recently filed Form 10-K. The parties disclaim any obligation to update forward-looking statements.

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SOURCE Amylin Pharmaceuticals, Inc.

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/Web site: <http://www.BYETTA.com> /

/Web site: <http://www.lillydiabetes.com> /

/Web site: <http://www.lilly.com> /

/Web site: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf /

/Web site: <http://www.amylin.com> /

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CO: Amylin Pharmaceuticals, Inc.; Eli Lilly and Company; Alkermes, Inc.

ST: California, Indiana, Massachusetts

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